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| APPLICATION NO.          | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 10/063,159               | 03/26/2002  | Roger Akerlund       | 47865.272256        | 2733             |
| 28694                    | 7590        | 03/22/2006           | EXAMINER            |                  |
| NOVAK DRUCE & QUIGG, LLP |             |                      | SCHELL, LAURA C     |                  |
| 1300 EYE STREET NW       |             |                      | ART UNIT            |                  |
| 400 EAST TOWER           |             |                      | PAPER NUMBER        |                  |
| WASHINGTON, DC 20005     |             |                      | 3767                |                  |

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/063,159

Applicant(s)

AKERLUND ET AL.

Examiner

Laura C. Schell

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 January 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 2-7, 10, 11, 13-14, 18-19, 22-25, 28, 29, 31-32, 34-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 8, 9, 12, 15-17, 20, 21, 26, 27, 30 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 11 and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/23/05.

Applicant previously elected species D, which was held to encompass claims 1-33. The previous examiner working on this application subsequently withdrew claims 2-7, 10, 13-14, 18-19, 22-25, 28 and 31-32. However, after reviewing the application the current examiner found that claims 11 and 29 are also drawn to a non-elected species, as they claim an "annular capsule member" which is not disclosed in species D (Fig. 5).

Currently, claims 1, 8, 9, 12, 15-17, 20-21, 26, 27, 30 and 33 are pending in this office action.

Phone calls to Tracy Druce were placed on 3/9/06 and 3/10/06 and voicemail messages were left to try and resolve the issues set forth in the drawing objections, however the issues were not resolved over the phone.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the claimed "inlet port further comprising a first luer-lock connector, and said cap further comprising a second luer-lock connector for attachment to said luer-lock connector" as claimed in claim 1, must be shown or the feature canceled from the claim. As the claim stands currently, the elected species D (Fig. 5) does not show that the second luer-lock connector

directly connects to the first luer-lock connector. Instead, Fig. 5 shows that the second luer-lock connector connects to intermediary tubing. Therefore, claim 1, and consequently all dependent claims, does not read on species D (Fig. 5).

Furthermore, the claimed "second luer-lock connector further comprising a pierceable closure" in claims 8 and 26 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Objections***

Claims 42 and 43 are objected to because of the following informalities:

Previously claims 31-49 were withdrawn, however, the amended claims sheet does not indicate that claims 42 and 43 have been withdrawn, instead they are indicated as "(Original)". Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8, 9, 12, 15-17, 20-21, 26, 27, 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaillancourt (US Patent No. 5,897,526) in view of Karrasch et al. (US Patent No. 5,279,605) and Post et al. (US Patent No. 5,492,531). Vaillancourt discloses a fluid transfer assembly comprising: a fluid container (Fig. 1, 10) having an infusion fluid, a drug container (25) having a medical substance, a fluid barrier (44) controlling fluid passage between said drug container and said fluid container further containing an inlet port (21) and said drug container further comprising a cap (34). Vaillancourt further discloses that the drug container comprises a neck (Fig. 1, between 42 and 32) and that the cap (34) comprises locking members (37). The cap also comprises a protruding member (Figs. 2-5, element 31, which as seen in Fig. 12 continues as a channel/duct and becomes element 20). Vaillancourt further discloses

Art Unit: 3767

that the assembly comprises a clamping member (22) in which the second fluid duct (starting as 31 and ending as 20 in Fig. 12) is compressed and closed. Vaillancourt also discloses a hollow spike member (Fig. 1, outlined in dashed lines). Vaillancourt further discloses that an infusion line is connected to the assembly (Fig. 12) and that a second clamping member is provided (Fig. 12, 53). Vaillancourt also discloses that the drug container is made from glass and plastic (col. 7, lines 11-15).

Vaillancourt further discloses that the cap has a connector (near 39 and 40) and that the inlet port has a connector (where 21 connects to 18). However, Vaillancourt does not disclose expressly that the connectors are luer-lock connectors. However, it is well known in the art that luer-lock connectors are used in these infusions systems as connectors as evidenced by Karrasch et al. (US Patent No. 5,279,605) in which Fig. 1, element 18 is a luer connector (col. 4, lines 16-20) which is similar to what is disclosed in Fig. 5 of applicant's drawings. Furthermore, Vaillancourt discloses that the fluid barrier is pierceable, but does not expressly disclose that the barrier is rupture-able. However, it is well known in the art that drug containers can have rupture-able membranes as well, as evidenced by Post et al. (US Patent No. 5,492,531) in which membrane (Fig. 2, 92) is indicated as rupture-able (col. 4, lines 51-55). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Vaillancourt with the luer-lock connectors as taught by Karrasch and the rupture-able membrane as taught by Post in order to provide a fluid transfer assembly that has a standard type of connector for versatility in use and in order to provide an alternative type of membrane closing the drug container.

Art Unit: 3767

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LCS

*LCS*



**MICHAEL J. HAYES  
PRIMARY EXAMINER**